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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 6

Application Number:	09/029,479
Filing Date:	February 24, 1998
First Named Inventor:	Sara Lavi
Group Art Unit:	
Examiner Name:	
Attorney Docket Number:	2290.00061

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document Kind Code ² Number (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
qW		4,666,828	Gusella	05-19-1987	
		4,683,202	Mullis	07-28-1987	
		4,736,866	Leder et al.	04-12-1988	
		4,801,531	Frossard	01-31-1989	
		5,175,383	Leder et al.	12-29-1992	
		5,175,384	Krimpenfort et al.	12-29-1992	
		5,175,385	Wagner et al.	12-29-1992	
		5,192,659	Simons	03-09-1993	
		5,221,778	Byrne et al.	06-22-1993	
		5,272,057	Smulson et al.	12-21-1993	
		5,288,846	Quertermous et al.	02-22-1994	
		5,298,422	Schwartz et al.	03-29-1994	
		5,347,075	Sorge	09-13-1994	
		5,360,735	Weinshank et al.	11-01-1994	
		5,387,742	Cordell	02-07-1995	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Office ³ Number ⁴ (if known)	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
qW		WO 93/14200		TSI Corporation	07-22-1993	
		WO 94/06908		The Regents of the University of California	03-31-1994	
		WO 94/23049		The Johns Hopkins University	10-13-1994	
		WO 94/28123		Ontario Cancer Institute	12-08-1994	T ⁶

Examiner Signature	<i>Joe Woda</i>	Date Considered	1/21/01
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Sheet 2 of 6

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First Named Inventor: Sara Lavi
Group Art Unit:
Examiner Name:
Attorney Docket Number: 2990.00061

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T2

- 9W
- ALADJEM AND LAVI, 1992. The mechanism of carcinogen-induced DNA amplification: In-vivo and in-vitro studies. *Mutation Res.* 276:339-344.
 - ATCHISON ET AL., 1965. Adenovirus-associated defective virus particles. *Science* 149:754-756. [n/a - will mail in]
 - ATHERTON-FESSLER ET AL. (1993) Reversible tyrosine phosphorylation and cell cycle control. *Semin. Cell. Biol.*, 4(6):433-42. [n/a - will mail in]
 - BANTEL-SCHAAL AND ZUR HAUSEN (1988a) Adeno-associated viruses inhibit SV40 DNA amplification and replication of herpes simplex virus in SV40-transformed hamster cells. *Virology*, 164:64-74.
 - BANTEL-SCHAAL AND ZUR HAUSEN (1988b) Dissociation of carcinogen-induced SV40-DNA-amplification and amplification of AAV DNA in a Chinese hamster cell line. *Virology*, 166:113-122.
 - BERNS, 1990. Parvovirus replication. *Microbiol. Rev.* 54:316-329.
 - BROWN, ET AL. (1996) A defect in nurturing in mice lacking the immediate early gene *fosB*. *Cell*, Vol 86, pp. 297-309.
 - BURKE AND OLSON, 1991. Preparation of Clone Libraries in Yeast Artificial-Chromosome Vectors" in *Methods in Enzymology*, Vol. 194, "Guide to Yeast Genetics and Molecular Biology", eds. C. Guthrie and G. Fink, Academic Press, Inc., Chap. 17, pp. 251-270.

9W

 - BURSTYN, 1993. Suppression of SV40 DNA amplification by Adeno Associated virus. M.Sc. Thesis. Tel Aviv University. [n/a - will mail in]
 - CAPECCHI, 1989. Altering the genome by homologous recombination. *Science* 244:1288-1292.
 - CASTO AND GOODHEART, 1972. Inhibition of adenovirus transformation in vitro by AAV-1. *Proc. Soc. Exp. Biol. Med.* 140:72-78. [n/a - will mail in]
 - CECH (1986) "RNA as an Enzyme", *Scientific American*, 255:64-75
 - CECH (1990) "Self-Splicing of Group I Introns", *Annu. Rev. Biochem.* 59:543-568
 - CHAMBERS AND DAHMUS, 1994. Purification and characterization of a phosphatase from HeLa cells which dephosphorylates the c-terminal domain of RNA polymerase II. *J. Biol. Chem.* 269(42):26243-26248.
 - CHAMBERS ET AL. (1995) The activity of COOH-terminal domain phosphatase is regulated by a docking site on RNA polymerase II and by the general transcription factors IIF and IIB. *Journal of Biological Chemistry*, 270(25):14962-14969.
 - CHEUNG ET AL, 1980. Integration of the Adeno-associated virus genome into cellular DNA in latently infected human Detroit 6 cells. *J. Virol.* 33:739-748.
 - COHEN, 1989. The structure and regulation of protein phosphatases. *Annu. Rev. Biochem.* 58:453-508.
 - COHEN, P. 1991. Classification of protein-serine/threonine phosphatases: identification and quantitation in cell extracts. *Methods. Enzymol.* 201:389-399.

Joe Wanta 1/23/01

not present
CEUKOR, et al, 1984. Biology of adeno-associated virus. In: Berns, K.I. (Ed.) The Parvoviruses. Plenum Press, New York, pp. 33-66. [n/a - will mail in]

GW • DAVIES ET AL., 1992. Targeted alterations in yeast artificial chromosomes for inter-species gene transfer. Nucleic Acids Research, 20(11):2693-2698.

GW • DICKINSON ET AL., 1993. High frequency gene targeting using insertional vectors", Human Molecular Genetics, 2(8):1299-1302.

GW • DE LA MAZA AND CARTER, 1981. Inhibition of Adenovirus oncogenicity by Adeno-associated virus DNA. J. Natl. Cancer Inst. 67:1323-1326.

GW SEP 25 1993 PRESENT
PATENT & TRADEMARK OFFICE • EDEB ABD CEDAR (1994) Role of DNA methylation in the regulation of transcription. *Curr. Opin. Genet. Dev.*, 4(2): 255-9. [n/a - will mail in]

GW FODOR ET AL, 1993. Multiplexed biochemical assays with biological chips, Nature 364:555-556.

GW • FUKUNAGA, ET AL, 1993. Dephosphorylation of autophosphorylated Ca²⁺/calmodulin-dependent protein kinase II by protein phosphatase 2C. J. Biol. Chem. 268:133-137.

GW • GAVRIELI, ET AL, 1992. Identification of programmed cell death in situ via specific labeling of nuclear DNA fragmentation. J. Cell. Biol. 119:439-501. [n/a - will mail in]

GW • GEORG-FRIES, ET AL, 1984. Analysis of proteins, helper dependence, and seroepidemiology of a new human parvovirus. Virology 134:64-71.

GW • GILBOA, ET AL, 1986. Transfer and expression of cloned genes using retroviral vectors. BioTechniques 4(6):504-512.

GW • GOSSEN AND BUJARD, 1992. Proc. Natl. Acad. Sci. USA 89, 5547-5551. [n/a - will mail in]

GW • HAMPEL ET AL. (1993) "The Hairpin Ribozyme", *Methods: A Companion to Methods in Enzymology* 5:37-42

GW • HERMONAT, 1989. The Adeno-associated virus rep78 gene inhibits cellular transformation induced by Bovine Papillomavirus. Virology. 172:253-261.

GW • HERMONAT, 1994. Down regulation of the human c-fos and c-myc proto-oncogene promoters by Adeno-associated virus rep78. Cancer Lett. 81:129-136.

GW • HUXLEY ET AL., 1991. The human HPRT gene on a yeast artificial chromosome is functional when transferred to mouse cells by cell fusion. Genomics, 9:742-750 (1991).

GW • INOUYE, 1988. Antisense RNA: its functions and applications in gene regulation - a review. Gene. 72:25-34. [n/a - will mail in]

GW • JAKOBOWITS ET AL., 1993. Germ-line transmission and expression of a human-derived yeast artificial chromosome, Nature, 362:255-261.

GW • JUSTEMENT ET AL. (1994) Regulation of B-cell activation by CD45: a question of mechanism. *Immunol. Today*, 15(9):399-406. [n/a - will mail in]

GW • KAFRI, ET AL, 1992. Developmental pattern of gene-specific DNA methylation in mouse embryo and germ line. Genes Dev. 6:705-714. [n/a - will mail in]

GW • KATZ AND CARTER, 1986. Effect of adeno-associated virus on transformation of NIH 3T3 cells by ras gene and on tumorigenicity of an NIH 3T3 transformed cell line, Cancer Research, 46:3023-3026.

GW • KAWASAKI, 1990. Amplification of RNA. In: PCR protocols: A Guide to Methods and Applications, Innis MA, Gelfand DH, Sninsky JJ, White TJ, eds. Academic Press, pp21-27.

GW • KIRSCHSTEIN, et al, 1968. Inhibition of adenovirus 12 oncogenicity by adeno-associated virus. Proc. Soc. Exp. Biol. Med. 128:670-673.

GW • KLEINSCHMIDT ET AL. (1995) Sequence elements of the adeno-associated virus rep gene required for suppression of herpes-simplex-virus-induced DNA amplification. *Virology*, 206:254-262.

GW • LAMB ET AL., 1993. Introduction and expression of the 400 kilobase precursor amyloid protein gene in transgenic mice", Nature Genetics, 5:22-29.

GW • LAU AND BAYLINK (1993) Phosphotyrosyl protein phosphatases: potential regulators of cell proliferation and differentiation. *Crit. Rev. Oncog.*, 4(4):451-71. [n/a - will mail in]

1/23/01



9W LAVI, 1981. Carcinogen mediated amplification of viral DNA sequences in SV40 transformed Chinese hamster embryo cells. Proc. Natl. Acad. Sci. USA 78:6144-6148.

not present LEONARD AND BERNS, 1994. Adeno-associated viruses type 2: a latent life cycle. Proc. Natl. Acad. Sci. USA. 91:29-52. [n/a - will mail in]

LIANG AND PARDEE, 1992. Differential display of eukaryotic messenger RNA by means of the polymerase chain reaction. Science 257:967-971. [n/a - will mail in]

LICHTER, ET AL., 1990. High-resolution mapping of human chromosome 11 by in situ hybridization with cosmid clones. Science 247:64-69.

MANN ET AL., 1992. Mammalian protein serine/threonine phosphatase 2C: cDNA cloning and comparative analysis of amino acid sequences. Biochim. Biophys. Acta 1130:100-104.

MARTIN-GALLARDO ET AL. (1992) Automated DNA sequencing and analysis of 106 kilobases from human chromosome 19q13.3. Nature Genetics, Vol. 1, pp. 34-39.

MAYOR, ET AL, 1973. Influence of adeno-associated satellite virus on adenovirus-induced tumors in hamsters. Nature New Biol. 261:44-46. [n/a - will mail in]

MAYOR, ET AL, 1976. Antibodies to adeno-associated satellite virus and herpes simplex in sera from cancer patients and normal adults. Am. J. Obstet. Gynecol. 126:100-104.

not present McCLELLIAND, ET AL, 1995. RNA fingerprinting and differential display using arbitrarily primed PCR. TIG. 11:242-246. [n/a - will mail in]

9W McGOWAN AND COHEN (1987) Identification of two isoenzymes of protein phosphatase 2C in both rabbit skeletal muscle and liver. Eur. J. Biochem., 166:713-722. [n/a - will mail in]

9W McGOWAN AND COHEN, 1988. Protein phosphatase-2C from rabbit skeletal muscle and liver: an Mg 2+ dependent enzyme. Methods Enz. 159:416-426.

9W NISHIKAWA ET AL (1995) Up-regulation of protein serine/threonine phosphatase type 2C during 1 alpha, 25-dihydroxyvitamin D3-induced monocytic differentiation of leukemic HL-60 cells. FEBS Lett., 375:299-303. [n/a - will mail in]

not present OHISHI, S. ET AL., Biochem. Intl. 28:345-351, 1992. [n/a - will mail in]

9W ORITA M, ET AL. Detection of polymorphisms of human DNA by gel electrophoresis as single-strand conformation polymorphisms. Proc Natl Acad Sci USA 1989; 86:2766-2770

OSTROVE, ET AL, 1981. Inhibition of adenovirus-transformed cell oncogenicity by adeno-associated virus. Virology 113:521-533.

PEASE ET AL., 1994. Light-generated oligonucleotide arrays for rapid DNA sequence analysis. Proc. Natl. Acad. Sci. USA 91(11):5022-5026.

9W ROBINSON, ET AL, 1994. TPD1 of *Saccharomyces cerevisiae* encodes a protein phosphatase 2C-like activity implicated in tRNA splicing and cell separation. Mol. Cell. Biol. 14:3634-3645.

not present ROMMELAERE AND TATTERSALL, 1990. Tijssen P. (ed.), *Handbook of Parvoviruses*. CRC, Boca Raton, pp. 41- 85. [n/a - will mail in]

9W ROTHSTEIN, 1991. "Targeting, disruption, replacement, and allele rescue: integrative DNA transformation in yeast" in *Methods in Enzymology*, Vol. 194, "Guide to Yeast Genetics and Molecular Biology", eds. C. Guthrie and G. Fink, Academic Press, Inc., Chap. 19, pp. 281-301.

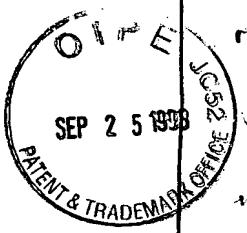
ROTH ET AL., 1990. Yeast alpha 2 repressor positions nucleosomes in TRP1/ARS1 chromatin. Mol. Cell. Biol., 10:2247-2260. [n/a - will mail in]

SAADAT, ET AL, (1994) Gene expression of protein phosphatases in rat ascites hepatoma cell lines. Cancer Detection and Prevention, 18(2):115-122.

SAJO AND MAYOR, 1979. Adenovirus-associated virus polypeptides synthesized in cells coinfecte with either adenovirus or herpesvirus. Virology 93:237-245. [n/a - will mail in]

9W SCHEDL ET AL., 1993. A yeast artificial chromosome covering the tyrosinase gene confers copy number-dependent expression in transgenic mice, *Nature*, 362:258-261.

Joe Wolden 1/23/01



- 9W ✓ SCHLEHOFER ET AL. (1983) Inhibition of initiator-induced SV40 gene amplification in SV40-transformed Chinese hamster cells by infection with a defective parvovirus. *Int. J. Cancer*, 32:591-595.
- ✓ SCHLEHOFER, (1994) The tumor suppressive properties of adeno-associated viruses. *Mutation Research*, 305:303-313.
- ✓ SCHLEHOFER, et al, (1986) Vaccinia virus, herpes simplex virus, and carcinogens induce DNA amplification in human cell line and support replication of helpervirus dependent parvovirus. *Virology*. 152:110-117.
- ✓ SCHLEHOFER AND ZUR HAUSEN, 1982. Induction of mutations within the host cell genome by partially inactivated herpes simplex virus type 1. *Virology* 122:471-475. [n/a - will mail in]
- ✓ SHIOZAKI AND RUSSELL (1995a) Counteractive roles of protein phosphatase 2C (PP2C) and a MAP kinase kinase homolog in the osmoregulation of fission yeast. *The EMBO Journal*, Vol. 14, No. 3, pp. 492-502.
- ✓ SHIOZAKI AND RUSSELL (1995b) Cell-cycle control linked to extracellular environment by MAP kinase pathway in fission yeast. *Nature*, Vol. 378, pp. 739-743.
- ✓ SHIOZAKI, ET AL, 1994. Protein phosphatase 2C, encoded by ptc1+, is important in the heat shock response of *Schizosaccharomyces pombe*. *Mol. Cell. Biol.* 14:3742-3751.
- ✓ SIEGL, ET AL, 1985. Characteristics and taxonomy of Parvoviridae. *Intervirology* 23:61-73. [n/a - will mail in]
- ✓ SODERLING (1993) Protein kinases and phosphatases: regulation by autoinhibitory domains. *Biotechnol. Appl. Biochem.*, 19(Pt.2):185-200. [n/a - will mail in]
- ✓ SOTOMAYOR, ET AL, 1991. Role of the tumor derived cytokines on the immune system of mice bearing a mammary adenocarcinoma. *J. Immunol.* 147:2816-2823. [n/a - will mail in]
- ✓ SPRECHER-GOLDBERGER, ET AL, 1971. Complement-fixation antibodies to adeno-associated viruses, adenoviruses, cytomegaloviruses and herpes simplex viruses in patients with tumors and in control individuals. *Am. J. Epidemiol.* 94:351-358.
- ✓ SULLIVAN (1994) "Development of Ribozymes for Gene Therapy", *J. Investigative Dermatology (Suppl)* 103:85S
- ✓ STRAUSS ET AL., 1993. Germ line transmission of a yeast artificial chromosome spanning the murine "1(I) collagen locus, *Science*, 259:1904-1907.
- ✓ TAMURA ET AL. (1989) Molecular cloning of rat type 2C (IA) protein phosphatase mRNA. *Proc. Natl. Acad. Sci. USA*, Vol. 86, pp. 1796-1800.

9W

- not present
- ✓ TAYLOR, 1980. *J. Histochem. Cytochem.* 28:1021. [n/a - will mail in]
- ✓ TRATSCHIN, 1985. Adeno associated virus vector for high frequency of integration, expression, and rescue of genes in mammalian cells. *Mol. Cell. Biol.* 5:3251-3260. [n/a - will mail in]

9W

- ✓ VINDELOV, ET AL, 1983. A detergent-trypsin method for the preparation of nuclei for flow cytometric DNA analysis. *Cytometry* 3:323-327. [n/a - will mail in]
- ✓ WALZ AND SCHLEHOFER 1992. Modification of some biological properties of HeLa cells containing Adeno associated virus DNA integrated into chromosome 17. *J. Virol.* 66:2990-3002.
- ✓ WANG ET AL. (1996) A Mg(2+)-dependent, Ca(2+)-inhibitible serine/threonine protein phosphatase from bovine brain. *The Journal of Biological Chemistry*, Vol. 270. No. 43, pp. 25607-25612.
- ✓ WEINBERG, R. (1996) E2F and cell proliferation: a world turned upside down. *Cell*, Vol. 85, pp 457-458. [n/a - will mail in]
- ✓ WENK AND MIESKES (1995) Cytosolic and nuclear localization of protein phosphatase 2C\$1 in COS and BHK cells. *Eur. J. Cell Biology*, 68:377-386. [n/a - will mail in]
- ✓ WERA AND HEMMINGS (1995) Serine/threonine protein phosphatases. *Biochem. J.*, 311:17-29. [n/a - will mail in]
- ✓ WIJSMAN, ET AL, 1993. A new method to detect apoptosis in paraffin sections: in-situ end-labeling of fragmented DNA. *J. Histochem. Cytochem.* 41:7-12. [n/a - will mail in]
- ✓ WINOCOUR, ET AL, 1992. Modulation of the cellular phenotype by integrated Adeno-associated virus. *Virology*. 190:316-329.
- ✓ YAKOBSON, ET AL, 1989. Replication of Adeno-associated virus in cells irradiated with UV light at 254 nm. *J. Virol.* 63:1023-1030.

9W

Doe Walker 1/23/01

90 ✓ YANG ET AL. (1995) Inhibition of cellular and SV40 DNA replication by the adeno-associated virus rep proteins. Virology, 207:246-250.

✓ YAKURA (1994) The role of protein tyrosine phosphatases in lymphocyte activation and differentiation. Crit. Rev. Immunol., 14(3-4):311-36. [n/a - will mail in]

✓ YOUNG AND MAYOR, 1979a. Adeno-associated virus - an extreme state of viral defectiveness. Prog. Med. Virol. 25:113-132. [n/a - will mail in]

YOUNG AND MAYOR, 1979b. Studies on the defectiveness of adeno-associated virus (AAV). 1. Effects of phosphonoacetic acid and 2-deoxy-D-glucose on the replication of AAV. Virology 94:323-341. [n/a - will mail in]



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